



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152, 156, 174 and 180

[EPA-HQ-OPPT-2012-0423; FRL-9977-08]

Withdrawal of Proposed Rules; Discontinuing Several Rulemaking Efforts Listed in the Semiannual Regulatory Agenda

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of proposed rules.

SUMMARY: EPA is withdrawing several proposed regulatory requirements described in the proposed rules identified in this document for which the Agency no longer intends to issue a final regulatory action. This document identifies the proposed rules and provides a brief explanation for the Agency's decision not to pursue a final action. The withdrawal of these proposed rules does not preclude the Agency from initiating the same or a similar rulemaking at a future date. It does, however, close out the entry for these rulemakings in EPA's Semiannual Regulatory Agenda. Should the Agency decide at some future date to initiate the same or similar rulemaking, it will add an appropriate new entry to EPA's Semiannual Regulatory Agenda to reflect the initiation of the action, and EPA will issue a new notice of proposed rulemaking.

DATES: As of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, the proposed rules published on November 23, 1994, at 59 FR 60519; November 23, 1994, at 59 FR 60525; June 26, 1996, at 61 FR 33260; and September 17, 1999, at 64 FR 50671, are withdrawn.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPPT-2012-0423, is available at <http://www.regulations.gov> or at the EPA Docket Center (EPA/DC), 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, for the OPP Docket it is

(703) 305-5805, and the telephone number for the OPPT Docket is (202) 566-0280. For more information about the docket and instructions about visiting the EPA/DC, go to <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Angela Hofmann, Director, Regulatory Coordination Staff (7101M), Office of Chemical Safety and Pollution Prevention, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0258; email address: hofmann.angela@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to those persons who follow proposed rules issued under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since others may also be interested, the Agency has not attempted to describe all the specific entities potentially interested.

II. Why is EPA Issuing this Withdrawal of Proposed Rules?

This document serves two purposes:

1. It announces to the public that EPA is withdrawing certain proposed rules for which the Agency no longer intends to issue a final rule.
2. It officially terminates the ongoing rulemaking activities, which allows the Agency to close out the individual rulemaking entries for these actions that appear in EPA's Semiannual Regulatory Agenda.

All agencies publish Semiannual Regulatory Agendas describing regulatory actions they are developing or have recently completed. These agendas are published in the *Federal Register*, usually during the spring and fall of each year, as part of the Unified Agenda of Federal Regulatory and Deregulatory Actions (Semiannual Regulatory Agenda). The Agency publishes

the EPA Semiannual Regulatory Agenda to update the public about: Regulations and major policies currently under development, reviews of existing regulations and major policies, and rules and major policies completed or canceled since the last Semiannual Regulatory Agenda.

The Semiannual Regulatory Agenda is often used as a tool to solicit interest and participation from stakeholders. As such, EPA believes that the public is best served by a Semiannual Regulatory Agenda that reflects active rulemaking efforts. The withdrawal of these inactive rulemaking efforts will streamline EPA's Semiannual Regulatory Agenda and allow the public to better identify and focus on those rulemaking activities that are active.

For the individual reasons described in this document, the Agency has decided not to complete these actions at this time. By withdrawing the proposed rules, the Agency is eliminating the pending nature of that regulatory action. Should the Agency determine to pursue anything in these areas in the future, it will create a new entry in EPA's Semiannual Regulatory Agenda and issue a new proposed rule.

III. Which Proposed Rules are Being Withdrawn?

This Unit identifies the proposed regulatory actions that are being withdrawn, provides a summary of what was proposed, and a brief explanation for the Agency's withdrawal. The "RIN" refers to the regulatory identification number assigned to the rulemaking effort in the Semiannual Regulatory Agenda.

A. Groundwater and Pesticide Management Plan Rule (PMP); RIN 2070-AC46.

1. *What was proposed?* On June 26, 1996 (61 FR 33260; FRL-4981-9), EPA issued a proposed rule to implement a key component of the Agency's 1991 Pesticides and Ground Water Strategy, and it reflected many years of discussions and input from States and other stakeholders. Through the development and use of State Management Plans (SMPs), EPA proposed to restrict the use of certain pesticides by providing States with the flexibility to protect the ground water in the most appropriate way for local conditions. This approach capitalized on the most effective

and efficient roles for State and Federal Government to collaborate in the protection of the nation's ground water resources. Using the proposed SMP approach, EPA proposed to restrict the legal sale and use of five pesticides that have been identified as either “probable” or “possible” human carcinogens--alachlor, atrazine, cyanazine, metolachlor, and simazine. Because of their potential to contaminate ground water, EPA had determined that these pesticides may cause unreasonable adverse effects on the environment in the absence of effective management measures provided by a SMP. The proposed rule announced that the labels of these pesticides would be changed to require use in accordance with an EPA-approved SMP, after a period of time allowed for development and approval of these SMPs. The proposed rule also contained proposed revisions to pesticide labeling regulations, in order to clarify general labeling requirements.

On February 23, 2000 (65 FR 8925; FRL-6491-1), EPA solicited public comments on additional information about metolachlor, which was one of the four pesticides in the proposed rule. In the proposed PMP rule, the Agency proposed, as a condition of continued use, that States and Tribes prepare chemical-specific management plans for four herbicides that have been shown to persist in the environment and leach to ground water, creating a potential unreasonable adverse effect on human health and the environment. Specifically, EPA sought comment on data provided to EPA pertaining to the products containing metolachlor, *S*-metolachlor, and *R*-metolachlor.

2. *Why is it being withdrawn?* Action on the proposal was delayed while the scope of the program described in the proposed rule was reconsidered to determine whether the program could be expanded to address water quality issues in addition to ground water, and to determine the best partnership approach to implementation. More important, the risk level associated with the named pesticides in the proposed rule was also reexamined as part of the FIFRA reregistration process concluded in 2006. As part of that process, EPA determined that all five of

the chemicals identified in the SMP proposal met the “no unreasonable adverse effects on the environment” standard for FIFRA registration without the steps identified in the proposed rule. These reregistration determinations necessarily mean that the rule is unnecessary to prevent unreasonable adverse effects on the environment, and EPA is therefore withdrawing its proposed rule.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP-36190.

B. Pesticides; Registration Requirements for Antimicrobial Pesticide Products; RIN 2070-AD14

1. *What was proposed?* On September 17, 1999, (64 FR 50671; FRL-5570-6), EPA issued a proposed rule to establish procedures for the registration of antimicrobial products, as well as implement certain new provisions of FIFRA, as amended by the Food Quality Protection Act (FQPA). In addition to registration procedures for antimicrobial products, EPA also proposed to establish labeling standards for antimicrobial public health products, which would ensure that these products are appropriately labeled for the level of antimicrobial activity they demonstrate; to modify its notification process for antimicrobial products to conform to the statutorily prescribed process; and to exempt certain antimicrobial products from FIFRA regulation. EPA proposed new procedures and provisions to streamline and improve the registration process, increase consistency and certainty for antimicrobial producers, reduce the timeframes for EPA decisions on antimicrobial registrations, increase public health protection by ensuring the continued efficacy of antimicrobial public health pesticides, and promote international harmonization efforts. EPA proposed to interpret the applicability of the new FIFRA definition of “pesticide” that excludes liquid chemical sterilants from FIFRA regulation and includes nitrogen stabilizers, and to describe requirements pertaining to use dilution labeling. EPA anticipated the proposed rule would provide technical, conforming and organizational

changes to portions of its regulations on pesticide registration and labeling for clarity and understanding. On November 16, 1999, (64 FR 62145; FRL-6393-8), EPA extended the comment period for the original proposed rule.

2. *Why is it being withdrawn?* On December 14, 2001 (66 FR 64759; FRL-6752-1) EPA issued a final rule, entitled “Pesticide Labeling and Other Regulatory Revisions,” effective February 12, 2002, revising certain labeling regulations for pesticide products for clarity and published an interpretation of the FIFRA as it applies to nitrogen stabilizers. The final rule also revised regulations that contain statutory provisions excluding certain types of products from regulation as pesticides.

The Pesticide Registration Improvement Act (PRIA), which was enacted in 2003, reauthorized October 1, 2007, by the Pesticide Registration Improvement Renewal Act (PRIA 2), and reauthorized again on October 1, 2012 by the Pesticide Registration Improvement Act (PRIA 3), established deadlines and pesticide registration service fees for registration actions. The category of action, the amount of the pesticide registration service fee, and the corresponding decision review periods by year are prescribed in these statutes. These statutory enactments were intended to create a more predictable evaluation process for affected pesticide decisions, and couple the collection of individual fees with specific decision review periods. They also promote shorter decision review periods for reduced-risk applications. EPA now actively provides guidance for PRIA-driven streamlined regulatory determinations for most major pesticide registration actions that is applicable to all pesticide registration types, not just antimicrobial products. (see PRIA guidance <http://www.epa.gov/pesticides/regulating/fees/index.htm>).

The passage and implementation of PRIA and the implementation of the Agency’s final rule regarding pesticide labeling and other regulatory revisions of December 14, 2001, have rendered the remainder of what was proposed in the proposed rule moot. For these reasons, EPA

is withdrawing the remainder of what was proposed in its proposed rule.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP-36190.

C. Plant-Incorporated Protectants (PIPs); Exemption for Those Derived through Genetic Engineering from Sexually Compatible Plants; RIN 2070-AD55.

1. *What was proposed?* On November 23, 1994 (59 FR 60519; FRL-4755-3) (when proposed, the RIN was 2070-AC02), EPA proposed to exempt from FIFRA regulation those plant-incorporated protectants (then called plant-pesticides) that are not likely to present new exposures to non-target organisms. This exemption was proposed based on the assumption that if a plant normally produces a pesticidal substance, organisms that normally come into contact with the plant have likely been exposed to the substance in the past, perhaps over long periods of time. No new exposures would be likely to occur, and based on long experience with plants in conventional agriculture, such PIPs would meet the FIFRA section 25(b)(2) exemption standard. In defining, for regulatory purposes, those substances for which no new exposures would occur, the Agency proposed to base its approach on the concept of sexual compatibility. Sexually compatible plants are more likely to share common traits than are unrelated plants. If the donor of the genetic material is sexually compatible with the recipient plant, it can be assumed that the genetic material is already present in the sexually compatible plant population and there would be no novel exposures. In the 1994 proposal, the proposed regulatory text did not specify how the genetic material of a plant-incorporated protectant or “PIP” could be moved from the donor to the sexually compatible recipient plant, whether through conventional breeding or genetic engineering techniques.

On July 19, 2001 (66 FR 37855; FRL-6760-4), EPA finalized part of its 1994 proposal thereby exempting certain plant-incorporated protectants moved among plants in a sexually compatible population. The 2001 rule defined sexually compatible as meaning a viable zygote is

formed only through the union of two gametes through conventional breeding. EPA did not in 2001 finalize that part of the proposal dealing with PIPs moved among plants in a sexually compatible population through genetic engineering but rather requested additional public comment on the issues raised by scientific information discovered between 1994 in 2001, in 1994 in public comment, and by issues raised by the 2000 report of the National Academies of Science (NAS) National Research Council (NRC).

2. *Why is it being withdrawn?* EPA is withdrawing this proposed action because as the Agency's experience with PIPs and greater scientific knowledge have increased, it has become evident to the Agency that were EPA to pursue an exemption for certain PIPs moved among plants in sexually compatible populations through genetic engineering, more appropriate, scientifically current criteria for describing the exempted PIPs should be developed rather than relying on the criteria proposed in 1994.

In 2001, EPA concluded that a high probability exists that PIPs moved between plants in sexually compatible populations through conventional breeding would not present novel exposures to nontarget organisms. Notwithstanding that conclusion, EPA could not (with the same level of confidence) draw the same conclusion for PIPs moved between plants in sexually compatible plant populations through genetic engineering given the limitations of the modification techniques available at that time. In addition, EPA came to agree with the 2000 NRC report that recommended that “[g]iven that transfer and manipulation of genes between sexually compatible plants could potentially result in adverse effects in some cases . . . EPA should reconsider its *categorical* exemption of *transgenic* [plant-incorporated protectants] derived from sexually compatible plants.” (NRC 2000 at p. 131, emphasis in original). The NRC report pointed out for example that the Agency's proposed language would exempt genetic material moved among plants in sexually compatible populations through genetic engineering without taking into consideration whether the moved genetic material would be expressed in the

same pattern and at the same levels as occurs naturally in the plant (NRC 2000 at p. 129). The proposal is not supported by a sufficient basis to finalize the proposed exemption, especially in light of the scientific developments that have taken place in the last decade.

Recently, newer, more precise techniques of genetic engineering have been developed based on scientific discoveries in genetics and molecular biology since the 1994 proposal and the 2001 rule were issued. These developments will allow the Agency to craft criteria that are scientifically more current and that more accurately describe the PIPs that would be exempted as well as procedures to better ensure that all the PIPs in an exempted category meet the FIFRA section 25(b)(2) exemption standard. Consequently, if EPA were to pursue such an exemption today, the Agency would issue a new proposed rule, based on knowledge of the types of products possible with the newest technology rather than issuing a final rule based on the previous proposals. Withdrawing the 1994 proposal does not preclude the Agency from initiating the same or similar regulatory action in the future. At that time, the Agency will initiate a new regulatory action and create a new entry for the Semiannual Regulatory Agenda. It is also worth noting that the Agency's proposal to exempt certain types of pesticide products from regulation under FIFRA is entirely a discretionary action; there is no requirement in FIFRA that the Agency promulgate a regulation to exempt products that might satisfy the exemption standard in FIFRA section 25(b)(2). EPA is therefore withdrawing the remainder of this proposal.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP-300369.

D. Plant-Incorporated Protectants (PIPs); Exemption for PIPs that Act by Primarily Affecting the Plant; RIN 2070-AD56

1. *What was proposed?* On November 23, 1994 (59 FR 60519; FRL-4755-3) (when proposed, the RIN was 2070-AC02), EPA proposed, under FIFRA section 25(b)(2), to exempt from most of the requirements of FIFRA those Plant-Incorporated Protectants (PIPs) (in 1994,

PIPs were called plant-pesticides (see 59 FR 60525; November 23, 1994)) that act primarily by affecting the plant under the assumption that such PIPs are less likely to be directly toxic to either target pests or to nontarget organisms. The criteria proposed at 40 CFR 174.5(b)(2) describe PIPs that act primarily by affecting the plant as a pesticidal substance so that the target pest is inhibited from attaching to the plant, penetrating the plant, or invading the plant's tissue in at least one of three ways: (a) The pesticidal substance acts as a structural barrier to attachment of the pest to the host plant, a structural barrier to penetration of the pest into the host plant, or a structural barrier to spread of the pest in the host plant, for example, through the production of wax or lignin, or length of trichomes (plant hairs); (b) The pesticidal substance acts in the host plant to inactivate or resist toxins or other disease-causing substances produced by the target pest; or (c) The pesticidal substance acts by creating a deficiency of a plant nutrient or chemical component essential for pest growth on/in the host plant.

EPA also indicated in 1994 that it was considering whether to extend this exemption to include substances such as plant hormones, because plant hormones act within the plant to “primarily affect the plant” and do not act directly on a target pest.

On July 19, 2001 (66 FR 37855; FRL-6760-4), EPA reopened the comment period on the proposed exemption to allow the public an opportunity to comment on the information, analyses, and conclusions pertaining to PIPs that act primarily by affecting the plant in the report issued in 2000 by the NRC of the NAS entitled “Genetically Modified Pest-Protected Plants: Science and Regulation” (National Research Council. 2000. National Academies Press, Washington, DC), and to comment on several risk issues received in public comment on the 1994 proposal (59 FR 60525, November 23, 1994).

2. *Why is it being withdrawn?* Because of new scientific discoveries in the area of genetics and molecular biology the Agency has concluded that neither the original 1994 proposal nor the subsequent 2001 supplemental proposal present a sufficient basis for making the

statutory finding required under FIFRA section 25(b)(2) to exempt this class of PIPs. Given the current state of genetic technology, it is possible that the exemption criteria set out in 1994 could exempt PIP products available today that pose different risks than the Agency envisioned when it initially proposed the criteria. In essence, the more limited technological capabilities and understanding of science in 1994 led EPA to propose criteria for a generic exemption that current technologies and scientific understanding have rendered inappropriate. While there may be some PIPs that act primarily by affecting the plant that would meet the FIFRA section 25(b)(2) standard for exemption, the Agency no longer considers its proposed criteria for a generic exemption to fairly restrict available products to only those that “are of a character which is unnecessary to be subject to” regulation under FIFRA. 7 U.S.C. 136w(b)(2). EPA is therefore withdrawing this proposal.

The decision to exempt pesticides under section 25(b) of FIFRA is entirely discretionary; there is no requirement that EPA promulgate pesticide exemptions. Withdrawing the proposal does not preclude the Agency from initiating regulatory action in the future for PIPs that act primarily by affecting the plant, e.g., exempting on a case-by-case basis a PIP that acts primarily by affecting the plant when that PIP can be shown to meet the FIFRA section 25(b)(2) exemption standard. At that time, the Agency would initiate a new regulatory action and create a new entry for EPA’s Semiannual Regulatory Agenda.

i. *Why the Proposed Exemption Criteria Would Exempt Pesticides that Do Not Meet FIFRA Section 25(b)(2) Safety Standard.* A number of advances in scientific knowledge accumulated since publication of the 1994 proposal to exempt PIPs that act primarily by affecting the plant have contributed to an understanding of how the proposed criteria would exempt from FIFRA requirements PIPs that do not meet the FIFRA 25(b)(2) exemption standard. For example, recent research into plant regulatory mechanisms, e.g., the discovery of, and elucidation of the role of interfering RNAs (RNAi), in gene expression, not available at the time

the 1994 proposal was published, contributed to the Agency's determination that the proposed exemption categories were constructed such that there are PIPs in the exempted categories that would not meet the FIFRA section 25(b)(2) standard. RNAi plays a key role in directing development of an organism, as well as controlling the various biological functions necessary to maintaining the life of an organism. RNAi is triggered by dsRNA, and while dsRNA can be native to the cell it can also be introduced from an external source. At the time the exemption was proposed, the role of dsRNA in controlling biological functions in the cell was unknown and the possibility that dsRNA could be introduced into the plant to affect the plant's behavior was not taken into consideration. Had such knowledge been available, the proposed criteria would have been based on substantively different logic.

ii. Consideration of the points made in the 2000 NRC Report. In withdrawing this proposal, EPA has also taken into consideration the points the 2000 NRC report made on the Agency's 1994 proposal to exempt from FIFRA requirements PIPs that act primarily by affecting the plant. The NRC report noted that the Agency's analysis did not consider all of the potential impacts on non-target species of all of the PIPs proposed for exemption, including the possibility that in some instances secondary metabolites affecting non-target organisms could be a by-product of a modification to create a PIP that acts primarily by affecting the plant. The NRC report concluded that based on its considerations a "[C]ategorical exemption under FIFRA might not be scientifically justifiable" (NRC 2000 at p. 133). Finally, the NRC report also cautioned the Agency that "genetic changes that result in production of a specific plant protectant can result in production of biologically active compounds other than the intended plant protectants" and cautioned that "EPA should be aware of those unintended changes" (NRC 2000 at p. 134). Upon further analysis, EPA has concluded that the generic criteria proposed in 1994 to allow exemption of PIPs, did not meet the FIFRA section 25(b)(2) exemption standard.

Given the large number of potential PIPs displaying a wide range of modes of action in

the categories circumscribed by each of the proposed exemption criteria, and advances in knowledge showing scientific concerns with the logic underpinning the criteria as constructed in 1994, the Agency cannot utilize the proposed criteria as a basis for this rulemaking. EPA is therefore withdrawing this proposal.

3. *Where can I get more information about this action?* The docket for this action is available under docket ID number OPP-300369. See also related dockets identified by the docket ID numbers OPP-300370 and OPP-300371.

Authority: 7 U.S.C. 136 *et seq.*, 21 U.S.C. 346.

Dated: April 25, 2018,

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